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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/108,189	07/01/1998	HOWARD TANNER	23660-00611	9021

25243 7590 03/19/2007
KELLEY DRYE & WARREN LLP
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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/108,189

Applicant(s)

TANNER ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 104-109, 115 and 120-135 is/are pending in the application.
- 4a) Of the above claim(s) 104-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 115 and 120-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 104-109 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05 December 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 115 and 120-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,885,238 to Stevens et al. (hereinafter "Stevens") in view of U.S. Patent No. 5,407,434 to Gross.

Stevens teaches the treatment of aneurysms (col. 17, line 9) using two sheaths (broadly shown in Figure 6, shown as 10 and 75, through which replacement valve 72 is introduced; the reference generally teaching that any of a number of instruments may be inserted through the sheaths; see col. 17, line 9). Stevens also teaches an inflatable cuff (Fig. 6) to hold a sheath in place, and a hemostasis valve (col. 42, line 39).

Stevens also teaches the use of a guidewire (col. 7, line 11). Steven teaches the use of

sheath device 422, a repair apparatus 322 and a numerous number of instruments that can be inserted into the repair apparatus 322 including an angioscope and penetration instruments.

Stevens, however, does not teach the use of 'gel-like' material. Gross teaches a similar device for sealing body-inserted instruments and uses a gel to seal around the instruments. The gel also seals the passage completely when the instruments are removed. It would have been obvious to one of ordinary skill in the art to modify the reference of Stevens by including the gel-like valve of Gross as a substantially equivalent alternative to the hemostatic valve.

Stevens and Gross, teach all the claimed subject matter except for repeating the insertion and removal of the aneurysm repair apparatus. However, it is commonly necessary for instruments to be inserted and removed from an introducer sheath(s) several times during the course of a surgical procedure. In fact, Stevens teaches in the abstract that the device may be used for aortic valve repair involving removal of the valve and replacement with a prosthetic valve. The removal, of course, would require removal of the tool, and the replacement would require reintroduction of tools. It would have been obvious to one of ordinary skill in the art to repeat the insertion and removal of the aneurysm repair tools, particularly if the repair was not successfully completed on the first attempt.

Response to Arguments

1. Applicant's arguments filed 29 January 2007 have been fully considered but they are not persuasive. Applicants have argued that Stevens does not teach two "introducer

sheaths." As shown in Fig 6, balloon catheter 10 is used to introduce valve delivery catheter 75, which is in turn used to induce the replacement valve 72. These two catheters 10 and 75 therefore constitute two introducer sheaths.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizabeth
Machili
3/13/07*

KEVIN C. SIMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Simons